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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/538,061  | 03/29/2006  | Mitsuhiko Haraguchi  | P28015              | 9213             |
| 7055  | 7590        | 11/17/2006           | EXAMINER            |                  |
| GREENBLUM & BERNSTEIN, P.L.C.<br>1950 ROLAND CLARKE PLACE<br>RESTON, VA 20191 |             |                      | ROBERTS, LEZAH      |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1614                |                  |

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |
|------------------------------|------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|                              | 10/538,061             | HARAGUCHI ET AL.    |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |
|                              | Lezah W. Roberts       | 1614                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-14 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1-14 is/are rejected.
- 7) Claim(s) 3 and 8 is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: ____                                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: ____  | 6) <input type="checkbox"/> Other: ____                           |

## DETAILED ACTION

### ***Claims***

#### **Claim Objections**

Claims 3 and 8 are objected to because of the following informalities: the claims are missing a period at the end of the sentences. Appropriate correction is required.

#### **Claim Rejections - 35 USC § 112 - Indefiniteness**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim 1 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It cannot be determined if this means, for instance, less than 1% or less than 5%. Therefore it cannot be determined what is covered by the term "substantially".

**Claim Rejections - 35 USC § 102 - Anticipation**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Takeuchi et al. (US 5,624,962).

Takeuchi et al. disclose drug compositions having the property of reversible thermosetting gelation that may be used in the oral cavity. The compositions may comprise drugs including anesthetics, antihistamines and mixtures thereof. Anesthetics include lidocaine hydrochloride and antihistamines include diphenhydramine hydrochloride (claims 2-3). The reference anticipates the claims insofar as it discloses a composition comprising a local anesthetic and an antihistamine.

2) Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Pan et al. (US 5,912,007).

Pan et al. disclose drug delivery systems, which may comprise drugs including antihistamines, anesthetics and mixtures thereof (col. 4, lines 14-20 and claim 2). Anesthetics include lidocaine and its pharmaceutically acceptable salts. Antihistamine

agents include diphenhydramine, hydroxyzine and their pharmaceutically acceptable salts<sup>1</sup>. The compositions are used to treat conditions of the upper respiratory tract, which include the mouth, encompassing claim 2. The reference anticipates the claims insofar as it discloses a composition comprising a local anesthetic and an antihistamine.

3) Claims 1, 3-7, 10 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Lapidus (US 5,543,148).

Lapidus discloses delivery systems for topical application of a treatment agent. The treatment agents include anesthetics, antihistamines and mixtures thereof (see Abstract). Anesthetics include lidocaine hydrochloride (col. 2, lines 49-50) and antihistamines include diphenhydramine hydrochloride (col. 3, lines 32-33). The reference anticipates the claims insofar as it discloses a composition comprising a local anesthetic and an antihistamine.

Claims 1-14 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

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<sup>1</sup> Lidocaine, diphenhydramine and hydroxyzine are commercially available as a hydrochloride salt. See Rxlist.com.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Lezah Roberts  
Patent Examiner  
Art Unit 1614

Frederick Krass  
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